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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,568	07/30/2001	Wataru Morikawa	20-48418	2810
2292	7590	11/18/2005	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,568

Applicant(s)

MORIKAWA ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-11, 13-15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) 5-10, 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 11, 15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Response to Arguments and Amendments

1. Claims 1, 3-11, 13-15 and 17 are pending.

Claims 5-10, 13 and 14, drawn to non-elected inventions are withdrawn from examination.

Claims 2 and 16 have been cancelled.

Claims 1, 3, 4, 11, 15 and 17 are examined on the merits.

2. Applicants are reminded that claim 16 has been cancelled and not amended as suggested in the Status of the Claims section of the Remarks submitted August 19, 2005, see page 6.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

4. The rejection of claims 1, 3, 4, 11, 15 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. Claims 2 and 16 have been cancelled. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants reiterate the features of the claimed invention, as well as submit Evidence A and Evidence B in aid of obviating the instant rejection. Applicants cite case law and surmise one of skill in the art would have the scientific literature at hand, such as the evidence submitted and realize and understand the scope of what is claimed. The evidence has been carefully reviewed, as well as the arguments, but found unpersuasive.

The claims continue to broadly state an aspartic enzyme that produces plasma protein fragments having an inhibitory activity of metastasis and growth of cancer. At first glance of the claims it is clear the claimed product is not isolated, nor described by any particular structure. And while the Examiner concurs with the Applicants in that they have listed that the N-terminus of the enzyme (SEQ ID NO: 1), remiss from the specification and the claims is information regarding the remaining residues, i.e. carboxy terminus. Applicants have not provided sufficient evidence that they were in possession of the wide breadth of proteins that could be regarded as an aspartic enzyme able to produce protein fragments. The simple statement of function for the claimed protein does not full the written description requirement. There is insufficient information provided substantiating Applicants are in possession of the plethora of aspartic enzymes, which the Applicants' claim.

Applicants are not entitled, nor does the specification evidence the possession of all aspartic enzymes that produce plasma protein fragments. Applicants are not

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permitted to claim the enumerable proteins simply referenced as aspartic enzymes that degrade or produce plasma proteins and have a N-terminal amino acid sequence of LVRIPLHKFT (SEQ ID NO: 1). Accordingly, Applicants are not entitled to the wide breadth of the claims at issue and the rejection is maintained.

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Claim Rejections - 35 USC § 102

5. The rejection of claims 1, 3, 4, 11, 15 and 17 under 35 U.S.C. 102(b) as being anticipated by Gately et al. (Cancer Research 56: 4887-4890, November 1, 1996/ IDS reference on sheet 1) is maintained. Claims 2 and 16 have been cancelled.

Applicants continue to vigorously argue that the enzyme of Gately is distinct from the claimed invention because "it is definitely true that Gately et al could not discover or isolate the aspartic enzyme of the present invention"., see bridging paragraph of pages 11 and 12 of the Remarks. Applicants state case law, which allegedly supports their position and point out passages within the Gately reference that purportedly teach away from the claimed invention. These arguments and points of view have been carefully considered, but found unpersuasive.

As noted in the 112, first paragraph rejection the claimed invention does not read on an isolated product and assuming arguendo Applicants' claims read on such, Gately's supernatant containing the enzyme was separated from the cell culture source

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thereby inherently isolated from the said source. Gately's factor derived from PC-3 would in fact contain the claimed enzyme. Unless the PC-3 cells of Gately were different from the PC-3 cells of Applicants the disclosed enzyme is one in the same as Applicants. And while Gately seemingly did not perform the proteinase inhibitor assay at the same pH as Applicants this does not teach away from the simple fact that enzyme of Gately contained in the PC-3 supernatant is the enzyme of Applicants.

Based on the analysis set forth and in the previous Action the prior art discloses the claimed invention and the inherent features necessarily flow from the said art and the rejection is maintained.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER



Alana M. Harris, Ph.D.
14 November 2005